

**"510(k) Summary"**

**JAN 09 2013**

Date Prepared: December 18, 2012

Manufacturer: Best Medical International, Inc.  
7643 Fullerton Road, Springfield, VA 22153  
Phone: (703) 451-2378  
Fax: (703) 451-4736.

Contact Person : Dharmendra Thakur  
Manager, Quality and Regulatory Affairs  
Phone: (703) 451-2378 Ext-162  
Fax: (703) 451-4736.

Trade Name: "Best<sup>®</sup> Localization Needle with I-125 Seed"

Common Name: Source, Brachytherapy, Radionuclide

Classification name: Radionuclide Brachytherapy Source (21 CFR 892.5730)

Predicate device: BrachySciences Radioactive Seed Localization Needle with AnchorSeed (K111979)

Description: "Best<sup>®</sup> Localization Needle with I-125 Seed" contains low activity Iodine seed (Best I-125- K912170). The Iodine-125 seed is loaded as loose or as stranded inside the needle. Most commonly, 18 gauge 5cm to 20 cm needles are used as a breast localization needle to facilitate the introduction of radionuclide seed into the breast cancer area. The devices are packaged in a pouch with label and provided sterile.

Intended Use: Best<sup>®</sup> Localization Needle with I-125 Seed, is a device intended to be used with or without absorbable strands to facilitate the introduction of a radionuclide (Iodine-125) seed to non palpable breast lesions for excision.

Summary of Substantial Equivalence: The technological characteristic and intended use of Best<sup>®</sup> Localization Needle with I-125 Seed is similar to the predicate device (BrachySciences Radioactive Seed Localization Needle with AnchorSeed). In summary, "Best<sup>®</sup> Localization Needle with I-125 Seed" as described in this submission is substantially equivalent to the predicate device.

7643 Fullerton Road, Springfield, VA 22153 USA  
phone 703 451 2378 800 336 4970 fax 703 451 5228  
[www.bestmedical.com](http://www.bestmedical.com)



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

C/O Mr. Dharmendra Thakur  
Manager, Quality and Regulatory Affairs  
Best Medical International  
7643 Fullerton Road  
SPRINGFIELD VA 22153

January 9, 2013

Re: K122704  
Trade/Device Name: Best® Localization Needle with I-125 seed  
Regulation Number: 21 CFR 892.5730  
Regulation Name: Radionuclide brachytherapy source  
Regulatory Class: II  
Product Code: KXX  
Dated: November 9, 2012  
Received: November 13, 2012

Dear Mr. Thakur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Michael D. O'Hara". The signature is fluid and cursive, with the first name "Michael" and last name "O'Hara" clearly legible, and a middle initial "D." in between.

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122704

Device Name: Best Localization Needle with I-125 Seed

Indications for Use:

The device is indicated as "single-use sterile device". Best® Localization Needle with I-125 Seed is indicated in the use for Breast Localization purpose under the direct supervision of a qualified physician.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health  
Office of *In Vitro* Diagnostic and Radiological Health

510(k)           K122704          

Page 1 of